

**Notice of Allowability**

Application No.

10/764,288

Applicant(s)

LIVNAH ET AL.

Examiner

Anish Gupta

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4-24-07.
2. ☒ The allowed claim(s) is/are 1,2,7-17 and 20-23.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

  
ANISH GUPTA  
PRIMARY EXAMINER

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Allen Fanucci on June 21, 2007.

The application has been amended as follows:

Claims 18-19 and 24 have been canceled.

Claim 7-14, 17 20 and 23 have been amended as follows:

7. The compound according to claim 1 wherein ~~Z comprises comprising the sequence~~ the compound comprises:

Arg-Pro-Arg-Thr-Glu-(bAla-5-mercaptoaminopropyl-isoquinoline)-Ser-Phe (SEQ ID NO: 3.).

8. The compound according to claim 1 wherein ~~Z comprises the sequence~~ the compound comprises:

Arg-Pro-Arg-Thr-Glu-(5-mercaptoaminopropyl-isoquinoline)-Ser-Phe (SEQ ID NO: 4).

9. The compound according to claim 1 wherein ~~Z comprises the sequence~~ the compound comprises:

Arg-Pro-Arg-Orn-Glu-(5-aminoethylsulfonamide-isoquinoline)-Ser-Phe (SEQ ID NO: 5).

10. The compound according to claim 1 wherein ~~Z comprises comprising the sequence~~ the compound comprises:

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Arg-Pro-Arg-Nva-Glu-(5-mercaptoaminopropyl-isoquinoline)-Ser-Phe (SEQ ID NO: 6)

11. The compound according to claim 1 wherein ~~Z comprises the sequence~~ the compound comprises:

Arg-Pro-Arg-Nle-Glu-(5-mercaptoaminopropyl-isoquinoline)-Ser-Phe (SEQ ID NO: 7).

12. The compound according to claim 1 wherein ~~Z comprises the sequence~~ the compound comprises:

Arg-Pro-Arg-Orn-Glu-(Gly-5-aminoethylsulfonamide)-Dab-Hol (SEQ ID NO: 8).

13. The compound according to claim 1 wherein ~~Z comprises comprising the sequence~~ the compound comprises:

Arg-Pro-Arg-Nle-Glu-(Gly-5-aminoethylsulfonamide)-Dab-Phe (SEQ ID NO: 9).

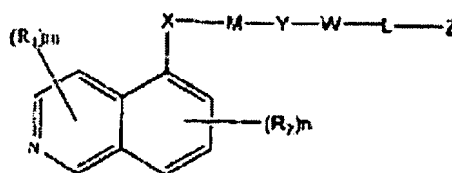
14. The compound according to claim 1 wherein ~~Z comprises the sequence~~ the compound comprises:

Arg-Pro-Arg-Nle-Glu-(Gly-5-aminoethylsulfonamide)-Dab-Hol (SEQ ID NO: 10).

17. A method of treatment of ~~a disease~~ diabetes, hemorrhagic shock, or inflammatory disease, comprising administering to a patient in need thereof a therapeutically effective amount of a compound according to claim 1.

20. A compound of Formula I:

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Formula I

wherein:

R1 and R2 are independently selected from the group consisting of hydrogen, a lower alkyl group, a lower alkoxy group, substituted or unsubstituted phenyl group, a lower alkyl substituted with at least one substituent selected from the group consisting of a phenyl group, a halogen, hydroxyl, thiol, nitro, cyano, or amino group; m and n are each independently 0-3;

X is selected from the group consisting of  $\text{SO}_2\text{-NH}$ , S and O ;

M represents substituted or unsubstituted alkylene of 1-4 carbon atoms;

Y is selected from the group consisting of amide, amine, urea, carbamate, hydrazine or sulfonamide;

W is absent or is selected from the group consisting of substituted or unsubstituted alkylene, aliphatic, aromatic or heterocyclic moiety, of 1-18 carbon atoms;

L is absent or is selected from the group consisting of amide, amine, urea, carbamate, hydrazine or sulfonamide; and

Z is a peptide or peptidomimetic moiety comprising one of the following sequences:

~~sequence:~~

Arg-Pro-Arg-Thr-Glu-(~~bAla-5-mercaptoaminopropyl-isoquinoline~~)-Ser-Phe (SEQ ID NO: 3);

Arg-Pro-Arg-Thr-Glu-(~~5-mercaptoaminopropyl-isoquinoline~~)-Ser-Phe (SEQ ID NO 4;

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Arg-Pro-Arg-Om-Glu-(~~5-aminoethylsulfonamide isoquinoline~~)-Ser-Phe (SEQ ID NO 5);

Arg-Pro-Arg-Nva-Glu-(~~5-mercaptoaminopropyl isoquinoline~~)-Ser-Phe (SEQ ID NO 6);

Arg-Pro-Arg-Nle-Glu-(~~5-mercaptoaminopropyl isoquinoline~~)-Ser-Phe (SEQ ID NO 7);

Arg-Pro-Arg-Om-Glu-(~~Gly-5-aminoethylsulfonamide~~)-Dab-Hol (SEQ ID NO 8);

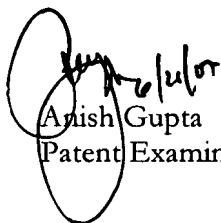
Arg-Pro-Arg-Nle-Glu-(~~Gly-5-aminoethylsulfonamide~~)-Dab-Phe (SEQ ID NO 9; or

Arg-Pro-Arg-Nle-Glu-(~~Gly-5-aminoethylsulfonamide~~)-Dab-Hol (SEQ ID NO 10);

and wherein Y, W if present, or L if present are linked to the Glu residues of the sequences.

23. A method of treatment of ~~a disease~~ diabetes, hemorrhagic shock, or inflammatory disease, comprising administering to a patient in need thereof a therapeutically effective amount of a compound according to claim 20.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

  
Anish Gupta  
Patent Examiner